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Direct pulp capping in primary molars

Submission date
29/10/2018

Recruitment status
No longer recruiting

Registration date
31/10/2018

Overall study status
Completed

Last Edited
05/02/2021

Condition category
Oral Health

[ ] Prospectively registered
[ ] Protocol
[ ] Statistical analysis plan
[X] Results
[ ] Individual participant data

Plain English summary of protocol

Background and study aims
Vital baby teeth with deep caries (decay and crumbling) can be treated in a variety of ways. When exposure of the pulp (the centre of the tooth) occurs in these teeth, a method called direct pulp capping (DPC) may be an excellent treatment of choice, as it might prevent unnecessary loss of the tooth structure. DPC builds a barrier over the site of exposure to protect the pulp. Calcium hydroxide is commonly used for DPC. However, using a combination of three antibiotics, caled 3Mix-MP, could reduce the inflammation and infection, and enhance the healing of the pulp. This study aims to compare the effectiveness of using 3Mix-MP and calcium hydroxide for DPC.

Who can participate?
Children who have primary molars with large caries

What does the study involve?
Chosen teeth are randomly allocated into two groups for DPC treatment with either 3Mix-MP or calcium hydroxide (CH). All teeth are assessed at 3, 6, 9 and 12 months after treatment and will be assessed radiographically after 6 and 12 months.

What are the possible benefits and risks of participating?
The treatment may prevent inflammation and abscesses, along with symptoms such as pain and swelling.
There are no known risks to participants, as any failed treatments will be re-done using another method.

Where I the study run from?
Department of Pediatric Dentistry, Tishreen University Latakia (Syria)

When is the study starting and how long is it expected to run for?
July 2016 to February 2019

Who is funding the study?
Tishreen University (Syria)

Who is the main contact?
1. Dr. Nabih Raslan (rasln.nabih@tishreen.edu.sy)
2. Dr. Hasan Ali (hasan.h.ali@outlook.com)

Contact information

Type(s)
Scientific

Contact name
Dr Nabih Raslan

ORCID ID
https://orcid.org/0000-0001-9967-9575

Contact details
Department of paediatric Dentistry
Faculty of Medical Dentistry
Tishreen University
Lattakia
Syria
00963

Type(s)
Scientific

Contact name
Dr Hasan Ali

ORCID ID
https://orcid.org/0000-0001-6959-7552

Contact details
Department of paediatric Dentistry
Faculty of Medical Dentistry
Tishreen University
Lattakia
Syria
00963

Additional identifiers

Protocol serial number
REF: 179/20

Study information

Scientific Title

Direct pulp capping (DPC) in primary molars using a combination of three antibiotics (3Mix-MP): a randomized parallel controlled trial

Acronym
Direct pulp capping (DPC)

Study objectives
Is using 3mix-mp in direct pulp capping in primary molars more effective than using calcium hydroxide?

Ethics approval required
Old ethics approval format

Ethics approval(s)
The Institutional Review Board of Tishreen University, 02/08/2016, Approval No. 3179

Primary study design
Interventional

Study design
Interventional double-blind two-arm randomised parallel controlled trial

Study type(s)
Treatment

Health condition(s) or problem(s) studied
Management of large carious lesions in primary teeth

Interventions
Participants are randomly allocated to either group A or group B using a simple randomisation technique.
Group A receive direct pulp capping using 3Mix-MP, whereas group B receive direct pulp capping using calcium hydroxide.
Participants are asked to attend follow-up examinations, with clinical evaluations at 3, 6, 9 and 12 months post-treatment and radiographic evaluations at 6 and 12 months.

Intervention Type
Procedure/Surgery

Primary outcome(s)
Clinical success rate of the materials, with treatment considered to be a success if the following clinical signs are absent:
1. Spontaneous pain
2. Redness or soft tissue swelling
3. Mobility
4. Draining sinus tracts
5. Sensitivity to vestibular palpation
Teeth will be assessed clinically at the baseline and 3, 6, 9 and 12 months post-treatment.

Key secondary outcome(s)

Radiographic success rate of the materials, with the treatment considered to be a success if the following radiographic signs are absent:
1. Internal or external pathological root resorption
2. Inter-radicular/periapical radiolucency
Teeth will be assessed radiographically at the baseline and at 6 and 12 months post-treatment.

Completion date
15/02/2019

Eligibility

Key inclusion criteria
1. Cooperative healthy children
2. Aged 5-11 years
3. Vital primary molars with large carious lesions that could be restored with composite
4. No history of spontaneous pain, pathological mobility, redness or swelling of the vestibule, draining sinus tracts, or sensitivity to vestibular palpation
5. Absence of internal or external root resorption or inter-radicular/apical radiolucency
6. Both children and their parents are able to attend a 12-month follow-up procedure

Participant type(s)
Healthy volunteer

Healthy volunteers allowed
No

Age group
Child

Lower age limit
5 Years

Upper age limit
11 Years

Sex
All

Total final enrolment
17

Key exclusion criteria
Any clinical or radiographic signs indicating non-vital teeth

Date of first enrolment
15/08/2017

Date of final enrolment
25/03/2018

Locations

Countries of recruitment
Syria

Study participating centre
Tishreen University
Department of Pediatric Dentistry
Lattakia
Syria
00963

Sponsor information

Organisation
Tishreen University

ROR
https://ror.org/04nqts970

Funder(s)

Funder type
Not defined

Funder Name
Tishreen University, Latakia. Syria (ref: 4075/20).

Results and Publications

Individual participant data (IPD) sharing plan
The datasets generated during and/or analysed during the current study are/will be available upon request from Dr. Nabih Raslan (raslan.nabih@tishreen.edu.sy), from 3 months after publication up to 3 years. Data will be available for researchers who provide a methodological sound proposal.

IPD sharing plan summary
Available on request

Study outputs

Output type	Details	Date created	Date added	Peer reviewed?	Patient-facing?
Results article	results	04/02/2021	05/02/2021	Yes	No
Basic results	conference abstract	14/02/2020	14/02/2020	No	No
Poster results		01/09/2019	22/10/2019	No	No